



Cancer Facts

Complementary And Alternative Medicine

Questions and Answers About Laetrile/Amygdalin

Complementary and alternative medicine (CAM)—also referred to as *integrative* medicine—includes a broad range of healing philosophies, approaches, and therapies. A therapy is generally called *complementary* when it is used *in addition to* conventional treatments; it is often called *alternative* when it is used *instead of* conventional treatment. (Conventional treatments are those that are widely accepted and practiced by the mainstream medical community.) Depending on how they are used, some therapies can be considered either complementary or alternative. Complementary and alternative therapies are used in an effort to prevent illness, reduce stress, prevent or reduce side effects and symptoms, or control or cure disease.

Unlike conventional treatments for cancer, complementary and alternative therapies are often not covered by insurance companies. Patients should check with their insurance provider to find out about coverage for complementary and alternative therapies.

Cancer patients considering complementary and alternative therapies should discuss this decision with their doctor or nurse, as they would any therapeutic approach, because some complementary and alternative therapies may interfere with their standard treatment or may be harmful when used with conventional treatment.

1. What is laetrile?

Laetrile is a compound that has been used as an anticancer treatment in humans worldwide. It is not approved by the Food and Drug Administration for use in the United States. The term “laetrile” is an acronym (laevorotatory and mandelonitrile) used to describe a purified form of the chemical amygdalin. Amygdalin is a plant compound that contains sugar and produces cyanide. Amygdalin is found in the pits



of many fruits and raw nuts. It is also found in other plants, such as lima beans, clover, and sorghum. Cyanide is believed to be the active cancer-killing ingredient in laetrile.

Although the names laetrile, Laetrile®, and amygdalin are often used interchangeably, they are not the same product. The chemical make-up of Laetrile® patented in the United States is different from the laetrile/amygdalin produced in Mexico. The patented Laetrile® is a semi-synthetic form of amygdalin, while the laetrile/amygdalin manufactured in Mexico is made from crushed apricot pits. The studies discussed in this fact sheet used either Mexican laetrile/amygdalin or Laetrile®. The generic term “laetrile” will be used throughout this fact sheet except in cases where the patented version of Laetrile® is known to have been used in a study.

2. What is the history of the discovery and use of laetrile as a complementary or alternative treatment for cancer?

Amygdalin was first isolated in 1830 and was used as an anticancer agent in Russia as early as 1845. Its first recorded use in the United States as a treatment for cancer was in the 1920s. The early pill form of amygdalin was considered too toxic, and work with the compound was discontinued. In the 1950s, a reportedly nontoxic, semi-synthetic form of amygdalin was developed and patented in the United States as Laetrile®. Laetrile gained popularity in the 1970s as a single anticancer agent and as part of a metabolic therapy program consisting of a special diet, high-dose vitamin supplements, and pancreatic enzymes (a group of proteins that aid in the digestion of food). By 1978, more than 70,000 people in the United States had reportedly been treated with Laetrile®.

3. How is laetrile administered?

Laetrile is administered by mouth (orally) as a pill. It can also be given by injection into a vein (intravenously) or muscle. Laetrile is commonly given intravenously over a period of time and then orally as maintenance therapy (treatment given to help extend the benefit of previous therapy).

4. Have any preclinical (laboratory and animal) studies been conducted using laetrile?

Preclinical studies have been conducted with laetrile either alone or in combination with other substances. These studies tested the benefits of laetrile against cancer; the side effects of laetrile treatment; where and how laetrile breaks down in the body; and the way laetrile and its breakdown products leave the body. Laboratory and animal studies have shown little evidence that laetrile is effective against cancer.

5. Have any studies of laetrile been conducted in people?

Although many anecdotal reports (incomplete descriptions of the medical/treatment history of one or more patients) and case reports (detailed reports of the diagnosis, treatment, and followup of individual patients) are available, they provide little evidence to support laetrile as a treatment for cancer.

- In a case series published in 1953, 44 cancer patients did not show any measurable response to treatment with laetrile. Most of the patients who showed some improvement also received radiation therapy or anticancer drugs, so it is impossible to determine which treatment produced the benefit.
- In another series of case reports published in 1962, 10 patients with metastatic cancer (cancer that has spread from one part of the body to another) were treated with a wide range of doses of intravenous Laetrile®. Pain relief was the primary reported benefit. Reduced swelling of lymph nodes and decreased tumor size were also reported. However, long-term followup with these patients was not performed, so it is not known how long the benefits lasted after treatment.
- Benzaldehyde, which is produced when laetrile is broken down by the body, has also been tested for anticancer activity in humans. In two clinical series (case reports of a number of patients who are treated consecutively in a clinic), patients with advanced cancer who had not responded to standard therapy were treated with benzaldehyde. Some patients experienced a complete response (the disappearance of all signs and symptoms of cancer), while some had a decrease in tumor size. The responses to benzaldehyde lasted as long as the treatment continued. Almost all of the patients had been treated previously with chemotherapy or radiation therapy, but it is not known how soon treatment with benzaldehyde began after the other treatment ended.
- In 1978, the National Cancer Institute (NCI) requested case reports from practitioners who believed their patients had benefited from treatment with laetrile. Ninety-three cases were submitted; 67 of these were complete enough to be evaluated. An expert panel concluded that two of the 67 patients had complete responses and four experienced a reduction in tumor size. Based on these six cases, NCI sponsored clinical studies with laetrile.

6. What clinical trials (research studies in humans) been conducted with laetrile?

Findings from only two clinical trials with laetrile have been published. These trials, sponsored by NCI, were conducted in the late 1970s and early 1980s.

- The first trial, a phase I study tested the doses, method of administration, and schedule of administration of amygdalin in six cancer patients. Researchers found

that amygdalin caused minimal side effects. However, two patients who ate raw almonds while taking amygdalin developed symptoms of cyanide poisoning.

- In 1982, a phase II study with 175 patients looked at which types of cancer might respond to treatment with amygdalin. Most of the patients in this study had breast, colon, or lung cancer. Amygdalin was administered by injection for 21 days, followed by oral maintenance therapy using doses and procedures similar to those evaluated in the phase I study. Vitamins and pancreatic enzymes were also given as part of a metabolic therapy program that also included dietary changes. One stomach cancer patient showed a decrease in tumor size, which was maintained for 10 weeks while the patient was on amygdalin therapy. In 54 percent of the patients, there was a measurable progression (growth) of cancer at the end of the treatment. All of the patients showed cancer progression 7 months after completing treatment. Some patients reported an improvement in their ability to work or do other activities, and other patients said their symptoms improved. However, these improvements did not last once treatment ended. On the basis of this study, NCI concluded that no further investigation of laetrile was necessary.

No controlled clinical trials (trials that include a comparison group of patients who receive no additional treatment, a placebo, or another treatment) of laetrile have been conducted.

7. Have any side effects or risks been reported from laetrile?

The side effects associated with laetrile treatment are like the symptoms of cyanide poisoning. The symptoms include nausea and vomiting, headache, dizziness, bluish discoloration of the skin due to a lack of oxygen in the blood, liver damage, abnormally low blood pressure, droopy upper eyelid, difficulty walking due to damaged nerves, fever, mental confusion, coma, and death. The side effects can be increased by eating raw almonds or crushed fruit pits; eating certain types of fruits and vegetables including celery, peaches, bean sprouts, and carrots; or taking high doses of vitamin C.

The side effects of laetrile appear to depend on the method of administration. More severe side effects are experienced when laetrile is given by mouth than when it is given by injection.

8. Is laetrile approved for use in the United States?

The Food and Drug Administration (FDA) has not approved laetrile as a treatment for cancer, although the drug is manufactured and distributed as a cancer treatment in Mexico. To conduct clinical drug research with humans in the United States, researchers must file an Investigational New Drug (IND) application with the FDA. In 1970, an application for an IND to study laetrile was filed by the McNaughton Foundation. This request was approved initially, but was later rejected because

animal studies showed that laetrile was not likely to be effective as an anticancer agent. In addition, there were questions about how the proposed study was to be conducted. However, because of several court cases in the 1970s that challenged the FDA's role in determining which drugs should be available to cancer patients, laetrile was legalized in more than 20 States. In 1980, the U.S. Supreme Court overturned decisions by the lower courts, reaffirming the FDA's position that drugs must be proven both safe and effective before widespread use in humans.

Variations in commercial preparations of laetrile have been documented in Mexico, which is the primary supplier of laetrile. Incorrect product labels have been found, and samples contaminated with bacteria and other substances have been identified.

9. When considering complementary and alternative therapies, what questions should patients ask their health care provider?

- What benefits can be expected from this therapy?
- What are the risks associated with this therapy?
- Do the known benefits outweigh the risks?
- What side effects can be expected?
- Will the therapy interfere with conventional treatment?
- Is this therapy part of a clinical trial? If so, who is sponsoring the trial?
- Will the therapy be covered by health insurance?

10. How are complementary and alternative approaches evaluated?

It is important that the same scientific evaluation which is used to assess conventional approaches be used to evaluate complementary and alternative therapies. A number of medical centers are evaluating complementary and alternative therapies by developing clinical trials to test them.

More information about how CAM approaches are evaluated can be found in the National Cancer Institute (NCI) fact sheet *Questions and Answers About Complementary and Alternative Medicine in Cancer Treatment*. This fact sheet can be accessed at http://cis.nci.nih.gov/fact/9_14.htm on the Internet, or by calling the Cancer Information Service (CIS) at 1-800-422-6237.

11. How can patients and their health care providers learn more about complementary and alternative therapies?

Patients and their doctor or nurse can learn about complementary and alternative therapies from the following Government agencies:

The **National Center for Complementary and Alternative Medicine** (NCCAM) at the National Institutes of Health (NIH) facilitates research and evaluation of complementary and alternative practices, and provides information about a variety of approaches to health professionals and the public.

NCCAM Clearinghouse
Post Office Box 7923
Gaithersburg, MD 20898-7923
Telephone: 1-888-644-6226 (toll free)
301-519-3153 (for International callers)
TTY (for deaf and hard of hearing callers): 1-866-464-3615
Fax: 1-866-464-3616
E-mail: info@nccam.nih.gov
Web site: <http://nccam.nih.gov>

NCCAM and the **NIH National Library of Medicine** (NLM) jointly developed **CAM on PubMed**, a free and easy-to-use search tool for finding CAM-related journal citations. As a subset of the NLM's PubMed bibliographic database, CAM on PubMed features more than 230,000 references and abstracts for CAM-related articles from scientific journals. This database also provides links to the Web sites of over 1,800 journals, allowing users to view articles in full-text. (A subscription or other fee may be required to access full-text articles.) CAM on PubMed is available through the NCCAM Web site at <http://nccam.nih.gov>. It can also be accessed at <http://www.ncbi.nlm.nih.gov/PubMed> by selecting "Limits" and choosing "Complementary Medicine" as a subset.

The **NCI Office of Cancer Complementary and Alternative Medicine** (OCCAM) coordinates the activities of the NCI in the area of complementary and alternative medicine (CAM). OCCAM supports CAM cancer research and provides information about cancer-related CAM to health providers and the general public via its Web site <http://cancer.gov/cam> on the Internet.

The **Food and Drug Administration** (FDA) regulates drugs and medical devices to ensure that they are safe and effective.

Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857
Telephone: 1-888-463-6332 (toll free)
Web site: <http://www.fda.gov/>

The **Federal Trade Commission** (FTC) enforces consumer protection laws. Publications available from the FTC include:

- "Who Cares: Sources of Information About Health Care Products and Services"
- "Fraudulent Health Claims: Don't Be Fooled"

Consumer Response Center
Federal Trade Commission
CRC-240
Washington, DC 20580
Telephone: 1-877-FTC-HELP (1-877-382-4357) (toll free)
TTY (for deaf and hard of hearing callers): 202-326-2502
Web site: <http://www.ftc.gov/>

The information in this fact sheet was adapted from the NCI's PDQ® summary Laetrile/Amygdalin. Full reference citations are listed at the end of the PDQ summary, which can be accessed at <http://cancernet.nci.nih.gov/treatment/cam.shtml> on the Internet. The PDQ summary can also be obtained by calling the Cancer Information Service (CIS). The CIS, a national information and education network, is a free public service of the NCI, the Nation's primary agency for cancer research. The toll-free phone number for the CIS is 1-800-4-CANCER (1-800-422-6237). For deaf and hard of hearing callers with TTY equipment, the number is 1-800-332-8615.

The information in this fact sheet is not presented as a substitute for informed medical advice. If you have any questions about your individual medical situation, please contact your doctor.

This fact sheet was reviewed on 10/10/01